

# **Using a Reamer-Irrigator-Aspirator Reduces Femoral Intramedullary Pressure During Simulated Total Knee Arthroplasty**

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**James Falk**

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## **Abstract**

Total knee arthroplasty is a common procedure to relieve pain and improve mobility of individuals with osteoarthritis of the knee. During the procedure, an alignment rod is forced down the canal of the femur to guide in the cuts of the femur for proper fitting of the prosthetic implant. However, inserting the femoral intramedullary alignment rod during total knee arthroplasty (TKA) can generate high intramedullary pressure, which increases the risk of intraoperative complications caused by fat embolism. Despite modifications to the surgical procedure, the best method to prevent this rise in pressure remains unknown. The reamer/irrigator/aspirator is a surgical instrument designed for use during femoral canal entry to increase the canal size and remove intramedullary fat and may prevent this pressure increase. We posed two hypotheses: (1) using the reamer/irrigator/aspirator system will result in lower maximum femoral intramedullary pressure than using only conventional instrumentation during the initial steps of a TKA; and (2) using the reamer/irrigator/aspirator system in the initial steps of TKA will result in a mean maximum intramedullary pressure below 200 mmHg, a threshold for fat embolism in a sheep model. A simulated TKA was performed on 14 cadaveric femurs to compare the femoral intramedullary pressure using both methods. Considerable decreases in femoral intramedullary pressure of 86% proximally and 87% distally were obtained by using the reamer/irrigator/aspirator system. The mean maximum pressure using the reamer/irrigator/aspirator system was less than 200 mmHg. Clinical studies would be required to confirm any reduction in complications using the reamer/irrigator/aspirator system.

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## Chapter 1 Introduction

Arthritis and other rheumatic conditions are among the most common chronic diseases, affecting 70 million U.S. adults in 2001<sup>22</sup>, and comprise the leading cause of disability among U.S. adults<sup>23</sup>. Osteoarthritis is degenerative form of arthritis in which the cartilage between two bones in a joint deteriorates due to atrophy, the joint spacing narrows and the bones rub against each other. This results in chronic pain and loss of motion in the joint. Osteoarthritis of the knee is the breakdown of the cartilage that lines the femur and tibia at their points of contact in the knee joint. (Figure 1, DePuy-Johnson and Johnson) There are over 3 million cases of osteoarthritis of the knee in the United States<sup>24</sup>. X-rays are a common way for diagnosing osteoarthritis (Figure 2). Currently, only the symptoms of osteoarthritis can be treated, there is no cure.



**Figure 1: Comparison of two knee joints**



**Figure 2: X-ray of knee joint with osteoarthritis**

A common surgical procedure to treat osteoarthritis of the knee is a total knee arthroplasty (TKA). TKA is a way to alleviate that pain and regain the motion by reconstructing the joint of the knee. The joint is replaced by prosthetic components (Figure 3). There was over 300,000 TKA performed in the United States in 2003<sup>25</sup>. The procedure involves a vertical incision of about 8 inches on the anterior surface of the knee joint. This exposes the distal end of the femur and proximal end of the tibia. Those sections of the bones are cut and shaped to allow for the fitting of the prosthetic components. To guide in the cutting of the femur for proper fitting of the prosthetic part, an intramedullary alignment rod

(Figure 4) is inserted down the femur's canal.



**Figure 3: Knee joint replaced with prosthetic components**



**Figure 4: Intramedullary alignment rod**



Fat embolism is a common intraoperative occurrence during TKA, which is detected in 46% to 65% of patients.<sup>11</sup> Since physicians are aware of this, all patients are given anticoagulants following the procedure. When embolism reaches clinically relevant levels, the most commonly observed symptoms are hypoxemia, shortness of breath, petechial rash, or an altered mental status.<sup>1,20</sup> If fat embolism becomes life-threatening, it is classified as fat embolism syndrome (FES).<sup>1,4,5,11,19,20</sup> Although FES is rare, with reported incidences as high as 1% of all TKAs, mortality rates can reach as high as 10% to 20% of diagnosed cases despite supportive care with anticoagulation therapy and ventilatory support.<sup>1,13,20</sup>

The etiology of fat embolism and FES is not completely known. Two theories have been proposed to describe the mechanism of FES: (1) the biochemical theory and (2) the mechanical theory.<sup>3,5,20</sup> The biochemical theory states circulating fatty acids directly affect the pneumocytes and disrupt gas exchange.<sup>3,20</sup> The mechanical theory assumes fat particles from the medullary canal of long bones, like the femur, enter the circulation and obstruct the capillaries.<sup>5,20</sup>

It is widely accepted that inserting instruments into the femoral canal during TKA and THA causes high intramedullary pressures, causing intramedullary contents to enter into the systemic circulation.<sup>4,8,13,20</sup> The number of fat particles observed in the lungs postoperatively correlates with increased femoral intramedullary pressure when a TKA is performed using conventional instrumentation (eg, drill, intramedullary alignment guide, and so on).<sup>10,16</sup> Although the exact femoral intramedullary pressure threshold that leads to fat embolism has not been studied in humans, a sheep model suggests emboli (bone marrow surrounded by a thrombotic aggregate) appear at intramedullary pressures above 200

mmHg.<sup>21</sup> Several researchers have explored the use of different shapes and sizes of TKA intramedullary instrumentation and different surgical steps in an effort to prevent elevating the femoral intramedullary pressure during surgery.<sup>6,14,19</sup> Previous experiments have shown over sizing the entry hole and using a fluted alignment rod had less increase in femoral intramedullary pressure than not oversizing the entry hole and using a rounded alignment rod.<sup>8, 19</sup> Over drilling, combined with changes in alignment rod shape and size, has not yielded consistent reduction in intramedullary pressure below a threshold that may induce embolic phenomena. Mueller et al<sup>15</sup> demonstrated pressure from reaming the intramedullary femoral canal is transmitted through the intramedullary fat and considerable reduction in pressure can occur if the fat is removed before reaming or introducing an unreamed nail. However, as a result of the high viscosity of the medullary particles, the suction tube used in the experiment clogged frequently and actually elevated femoral intramedullary pressure in some cases when the fat was being removed. They concluded new instrumentation should be developed to facilitate the removal of the femoral intramedullary fat contents before reaming the femoral canal for intramedullary nailing of a femoral fracture.

## **1.1 Focus of Thesis**

The focus of this thesis was on the effectiveness of a new instrument in reducing the risk of post operative fat embolism in a TKA. This instrument will be evaluated based on its ability to reduce the rise in femoral pressure during a simulated total knee arthroplasty. The new instrument, reamer/irrigator/aspirator system, was designed to be used after femoral canal entry to increase the canal size and aspirate the intramedullary fat and bony chips

generated while reaming. The design uses irrigation to decrease the viscosity of the fat while simultaneously aspirating the slurry that is created. We posed two hypotheses: (1) using the reamer/irrigator/aspirator system will result in lower femoral intramedullary pressures than using only conventional instrumentation during the initial steps of a TKA; and (2) using the reamer/irrigator/aspirator system in the initial technique will result in a mean maximum intramedullary pressure below 200 mmHg.

## **1.2 Significance of Research**

This research is significant because fat embolism is a very serious complication of total knee arthroplasty. Even though the serious form of fat embolism, fat embolism syndrome, only occurs in less than 1% of all total knee arthroplasties, it can often lead to death among patients. Surgeons are aware that fat embolism can occur following a TKA, so patients are given anticoagulant drugs following the procedure to reduce the risk of having a fat emboli block a blood vessel. Giving patients blood thinners leads to an increase hospital stay because patients will not be discharged following given those drugs for at least 24 hours. This research looks at the pressure rise in the femoral intramedullary canal from two different techniques to TKA.

A clinical trial of this experiment can test the two techniques risk of fat embolism by specifically looking at fat particles in the blood stream through a transesophageal echocardiography. If the clinical trial does show that the modified technique does not induce fat emboli into the blood stream, then patients may not need the anticoagulant drugs

following the procedure.

Before a clinical trial is performed to evaluate the difference in fat emboli between the two techniques, a simulated total knee arthroplasty is performed to ensure that other unforeseen complications do not develop. The implications of negative consequences of the surgery can be evaluated on the cadavers before the clinical study. This prevents any unnecessary liability if the simulated experiment is not successful using the modified technique. If the simulated technique is not successful or induces other complications from evaluating the simulated experiment, then the clinical experiment will not be performed.

### **1.3 Overview of Thesis**

This thesis is broken down to four chapters. Chapter 2 is written as a self contained abstract for presentation as a poster at the 54th annual meeting of the Orthopaedic Research Society held from March 2-5, 2008 in San Francisco, California. The co-authors of the presentation are Dr. Robert Siston, Dr. Cornel Van Gorp, James Green, and Stanley Kmiec. Chapter 3 is written as a self-contained journal article which is currently available electronically ahead of print in *Clinical Orthopaedics and Related Research*. The co-authors of the journal article are Dr. Robert Siston, Dr. Cornel Van Gorp, and Stanley Kmiec. Both papers present the experiment that is outlined in Chapter 1 and contain the results and conclusion of the experiment. Chapter 4, the conclusion, summarizes the key contributions of this dissertation, discusses additional applications of this research, and proposes future directions of study.

## **Chapter 2 Orthopaedic Research Society Poster Presentation Abstract**

### **2.1 Introduction**

Fat embolism is a common occurrence following total knee arthroplasty (TKA) [4, 5]. Previous research has shown a positive correlation between an increase in femoral intramedullary pressure and the number of fat particles observed in the lungs postoperatively when a TKA was performed using traditional instrumentation [10, 16]. Efforts to reduce the femoral pressure during TKA include using differently sized and shaped intramedullary instrumentation and over-drilling the canal [19], but these approaches have not eliminated the risk of post-operative embolism. Mueller et al [15] demonstrated in a cadaver study that evacuating the intramedullary contents of the femur prior to reaming decreases the pressure produced during instrument insertion.

This study compares the femoral intramedullary pressure during the initial steps of a simulated TKA performed with conventional instrumentation against the intramedullary pressure of a simulated TKA performed with conventional instrumentation and the Reamer Irrigator Aspirator (RIA, Synthes Philadelphia, PA). We hypothesize that using the RIA will result in lower femoral intramedullary pressures than using only conventional instrumentation during the initial steps of a total knee arthroplasty.

### **2.2 Methods**

We performed a simulated TKA on 14 femurs (7 pairs) from fresh-frozen cadavers.

The femurs had all soft tissues removed and were mounted horizontally to custom fixtures. Pressure transducers (Omega Engineering Inc, Stamford, CT) were mounted proximally and distally on the femur and took pressure readings at 100 Hz. An experienced orthopedic surgeon performed the initial steps of TKA on all specimens. On the left femurs, he opened the canal with an 8/12.7 mm step drill (Zimmer, Warsaw, IN) and inserted an 8 mm fluted alignment rod (Zimmer, Warsaw, IN). He opened the canal on the 7 right femurs with the same step drill, but then inserted a 2.5 mm ball tip reaming rod for the RIA, reamed the canal with a 12 mm RIA, and then inserted an 8 mm fluted alignment rod. During all simulated TKAs, intramedullary pressure was recorded with the pressure transducers.

We used the student's t-test to compare the maximum recorded pressure from performing the procedure with the two different methods. All statistical tests were performed using SPSS V 14.0 (SPSS Inc, Chicago, IL) and the level of significance was set at  $\alpha=0.05$ .

### **2.3 Results**

Using the RIA resulted in statistically significant lower femoral intramedullary pressures, 86% less proximally and 87% less distally, compared to performing the steps of a TKA with conventional instrumentation alone ( $p<0.001$ ). See Table 1. The maximum pressure with the initial conventional method of TKA occurred during the insertion of the alignment rod (Figure 7). Using RIA along with the conventional TKA method, the average maximum pressure occurred during insertion of the ball tip reaming rod (Figure 8).

## 2.4 Discussion

The data suggest that using the RIA during the initial steps of a TKA would result in lower femoral intramedullary pressure than using only conventional instrumentation and lead to a reduced risk of fat embolism. To our knowledge, this is the first instance of using the RIA for total knee arthroplasty, since the RIA was developed for femur fracture surgery. Even though the device was not designed specifically for TKA, our study yielded promising results. Future work should be conducted using RIA to investigate the reduced risk of fat embolism in a clinical setting.

We note several limitations. The use of cadaver bone cleaved of soft tissue may not perfectly model in vivo pressures. Soft tissues may increase the resistance to outflow of intramedullary contents, and the stripping of these soft tissues may have falsely depressed the intramedullary pressures recorded while inserting instrumentation into the canal. Additionally, there was no recording of the insertion force or speed of the alignment rods; previous experiments have established these two parameters play a role in increasing femoral intramedullary pressure.<sup>5</sup> Despite these potential limitations, the maximum intramedullary pressures recorded during the insertion of the alignment rod using conventional techniques in our experiment ( $630.04 \pm 320.85$  mmHg proximally and  $535.69 \pm 261.77$  mmHg distally) were comparable to the values recorded by Ries et al<sup>5</sup> ( $649.3 \pm 218.5$  mmHg) using the similar technique in vivo.

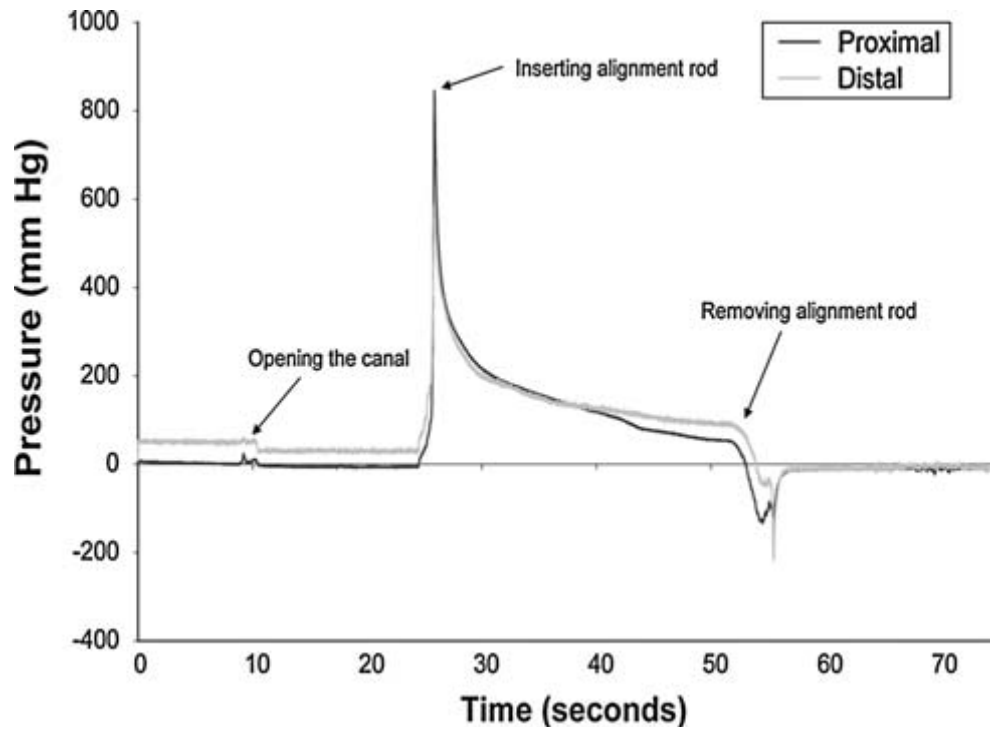


**Figure 5: Experimental Setup**



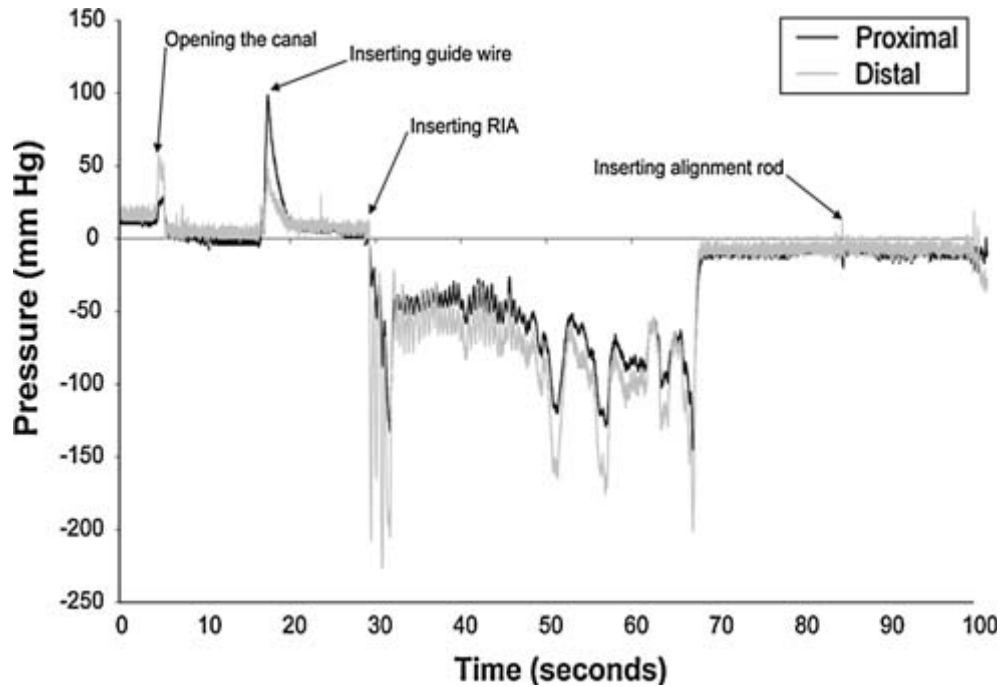
**Figure 6: Reamer Irrigator Aspirator**





**Figure 7: Conventional Method Pressure Reading**

Example pressure reading of conventional instrumentation for the initial steps of TKA.  
Highest femoral intramedullary pressure occurs during instrument insertion.



**Figure 8: Pressure Method Technique Using RIA**

Example pressure reading of using the RIA during the initial steps of TKA. Highest pressure occurs during insertion of the guide wire for the RIA. Inserting the alignment rod causes a negligible pressure increase after evacuating the contents of the medullary canal.

**Table 1: Peak femoral intramedullary pressure for initial steps of TKA**

Age	Gender	Canal Size (mm)		Left Femur - Without RIA		Right Femur - With RIA	
		left	right	Peak Proximal Pressure (mm Hg)	Peak Distal Pressure (mm Hg)	Peak Proximal Pressure (mm Hg)	Peak Distal Pressure (mm Hg)
86	Male	14	14	277.51	230.43	8.41	44.26
74	Male	12	13	359.82	272.75	25.83	37.91
91	Male	12	11	815.71	687.40	98.64	56.95
45	Female	9	10	845.78	587.98	106.55	46.38
50	Male	12	11	677.99	731.83	87.56	71.76
71	Female	12	11	315.50	327.75	212.61	118.31
72	Male	13	15	1118.00	911.66	87.56	95.04

**Table 2: Maximum Pressure Through Initial Steps of TKA**

steps	location	Max Pressure in mm Hg (mean $\pm$ standard deviation)	
		Conventional Method	Using RIA w/ Conv. Method
Opening the canal	Proximal	4.34 $\pm$ 13.18	8.86 $\pm$ 33.95
	Distal	41.54 $\pm$ 17.00	50.61 $\pm$ 34.18
Inserting ball tip reaming rod	Proximal	-	89.59 $\pm$ 66.04
	Distal	-	60.88 $\pm$ 22.83
Inserting RIA	Proximal	-	12.93 $\pm$ 9.82
	Distal	-	43.05 $\pm$ 24.58
Inserting Alignment	Proximal	630.04 $\pm$ 320.85	2.53 $\pm$ 10.08

## **Chapter 3: Clinical Orthopaedics and Related Research Publications**

### **The Reamer/Irrigator/Aspirator Reduces Femoral Canal Pressure in Simulated TKA**

Cornel C. Van Gorp, MD<sup>\*</sup>; James V. Falk<sup>†</sup>; Stanley J. Kmiec, Jr<sup>‡</sup>; and Robert A. Siston, PhD<sup>\*,†</sup>

From the <sup>\*</sup>Department of Orthopaedics and the <sup>†</sup>Mechanical Engineering Department, The Ohio State University, Columbus, OH; and <sup>‡</sup>Synthes, Inc, West Chester, PA.

Correspondence to: Robert A. Siston, PhD, Department of Mechanical Engineering, E318 Scott Laboratory, 201 W 19<sup>th</sup> Avenue, Columbus, OH 43210. Phone: 614-247-2721; Fax: 614-292-3163; E-mail: siston.1@osu.edu.

### **3.1 Abstract**

Inserting the femoral intramedullary alignment rod during total knee arthroplasty (TKA) can generate high intramedullary pressure, which increases the risk of intraoperative complications caused by fat embolism. Despite modifications to the surgical procedure, the best method to prevent this rise in pressure remains unknown. The reamer/irrigator/aspirator is a surgical instrument designed for use during femoral canal entry to increase the canal size and remove intramedullary fat and may prevent this pressure increase. We posed two hypotheses: (1) using the reamer/irrigator/aspirator system will result in lower maximum femoral intramedullary pressure than using only conventional instrumentation during the initial steps of a TKA; and (2) using the reamer/irrigator/aspirator system in the initial steps of TKA will result in a mean maximum intramedullary pressure below 200 mmHg. A simulated TKA was performed on 14 cadaveric femurs to compare the femoral intramedullary pressure using both methods. Considerable decreases in femoral intramedullary pressure of 86% proximally and 87% distally were obtained by using the reamer/irrigator/aspirator system. The mean maximum pressure using the reamer/irrigator/aspirator system was less than 200 mmHg. Clinical studies would be required to confirm any reduction in complications using the reamer/irrigator/aspirator system. intramedullary pressure below 200 mmHg.

### 3.2 Introduction

Fat embolism is a common intraoperative occurrence during TKA, which is detected in 46% to 65% of patients.<sup>11</sup> When embolism reaches clinically relevant levels, the most commonly observed symptoms are hypoxemia, shortness of breath, petechial rash, or an altered mental status.<sup>1,20</sup> If fat embolism becomes life-threatening, it is classified as fat embolism syndrome (FES).<sup>1,4,5,11,19,20</sup> Although FES is rare, with reported incidences as high as 1% of all TKAs, mortality rates can reach as high as 10% to 20% of diagnosed cases despite supportive care with anticoagulation therapy and ventilatory support.<sup>1,13,20</sup>

The etiology of fat embolism and FES is not completely known. Two theories have been proposed to describe the mechanism of FES: (1) the biochemical theory and (2) the mechanical theory.<sup>3,5,20</sup> The biochemical theory states circulating fatty acids directly affect the pneumocytes and disrupt gas exchange.<sup>3,20</sup> The mechanical theory assumes fat particles from the medullary canal of long bones, like the femur, enter the circulation and obstruct the capillaries.<sup>5,20</sup>

It is widely accepted that inserting instruments into the femoral canal during TKA and THA causes high intramedullary pressures, causing intramedullary contents to enter into the systemic circulation.<sup>4,8,13,20</sup> The number of fat particles observed in the lungs postoperatively correlates with increased femoral intramedullary pressure when a TKA is performed using conventional instrumentation (eg, drill, intramedullary alignment guide, and so on).<sup>10,16</sup> Although the exact femoral intramedullary pressure threshold that leads to fat embolism has not been studied in humans, a sheep model suggests emboli (bone marrow

surrounded by a thrombotic aggregate) appear at intramedullary pressures above 200 mmHg.<sup>21</sup> Several researchers have explored the use of different shapes and sizes of TKA intramedullary instrumentation and different surgical steps in an effort to prevent elevating the femoral intramedullary pressure during surgery.<sup>6,14,19</sup> Previous experiments have shown over sizing the entry hole and using a fluted alignment rod had less increase in femoral intramedullary pressure than not oversizing the entry hole and using a rounded alignment rod.<sup>8, 19</sup> Over drilling, combined with changes in alignment rod shape and size, has not yielded consistent reduction in intramedullary pressure below a threshold that may induce embolic phenomena. Mueller et al<sup>15</sup> demonstrated pressure from reaming the intramedullary femoral canal is transmitted through the intramedullary fat and considerable reduction in pressure can occur if the fat is removed before reaming or introducing an unreamed nail. However, as a result of the high viscosity of the medullary particles, the suction tube used in the experiment clogged frequently and actually elevated femoral intramedullary pressure in some cases when the fat was being removed. They concluded new instrumentation should be developed to facilitate the removal of the femoral intramedullary fat contents before reaming the femoral canal for intramedullary nailing of a femoral fracture.

A new instrument, reamer/irrigator/aspirator system, was designed to be used after femoral canal entry to increase the canal size and aspirate the intramedullary fat and bony chips generated while reaming. The design uses irrigation to decrease the viscosity of the fat while simultaneously aspirating the slurry that is created. This studies aim is to determine the effectiveness of this device in a total knee arthroplasty. We posed two hypotheses: (1) using the reamer/irrigator/aspirator system will result in lower femoral intramedullary pressures

than using only conventional instrumentation during the initial steps of a TKA; and (2) using the reamer/irrigator/aspirator system in the initial technique will result in a mean maximum intramedullary pressure below 200 mmHg.

### **3.3 Material and Methods**

We performed a simulated TKA on 14 femurs (seven pairs) from fresh-frozen cadavers. The specimens were from two female and five male donors between the ages of 45 and 91 (Table 1). Using the results from Mueller et al<sup>15</sup> as a guide, in which a  $405 \pm 309$  mmHg difference in femoral pressure was observed when fat was removed from the intramedullary canal, we conducted a power analysis and determined five cadaver specimens would be needed to ensure the experiment had a power above 0.8 to detect differences in pressure between the two techniques. We removed the soft tissues and the femurs were mounted diagonally in a bone clamp. Pressure ports, 7/16 inch in diameter, were drilled into the specimens at one-third and two-thirds their lengths proximal and distal to the midshaft. We then connected the ports by tubing to pressure transducers (PX209-30V15G5V; Omega Engineering Inc, Stamford, CT). The tubing from the pressure transducers was thread-sealed to the femurs and back-filled with water to eliminate air bubbles in the line. The pressure transducers took readings that were recorded at a frequency of 100 Hz. The data were read into an IBM laptop from the proximal and distal ports using data acquisition software (OMB-Tempbook-66; Omega Engineering Inc).

An experienced orthopaedic surgeon (CVG) performed the simulated TKA on all



specimens. The specimens were divided so the initial steps of a TKA using conventional methods were performed on the left femurs and the initial steps of a TKA, including the reamer/irrigator/aspirator system (RIA; Synthes, West Chester, PA), were performed on the right femurs. On the left femurs, the surgeon opened the canal with an 8/12.7-mm step drill (Zimmer, Warsaw, IN) and inserted an 8-mm fluted alignment rod (Zimmer). Approximately 5 seconds after the rod was fully inserted, he slowly extracted the rod. He opened the canal on the seven right femurs with the same 8/12.7-mm step drill, but then inserted a 2.5-mm ball tip reaming rod for the RIA, reamed the canal with a 12-mm RIA (Fig 1), and then inserted an 8-mm fluted alignment rod. During all simulated TKAs, we continually recorded the intramedullary pressure from the proximal and distal pressure transducers.

The pressure data from the RIA system were analyzed at four steps: (1) opening the canal; (2) inserting the ball tip reaming rod; (3) reaming with the RIA; and (4) inserting the alignment rod. Similarly, the pressure data from the conventional instrumentation were analyzed at two steps: (1) opening the canal and (2) inserting the alignment rod.

We chose to investigate pressure differences at only certain points of the procedure after performing a complete TKA on two specimens, one using conventional instrumentation and the other using the RIA system in conjunction with conventional instrumentation. We noted the only detectable pressure rise in the femoral intramedullary canal occurred while opening the canal and inserting the alignment rod while using the conventional instrumentation. Similarly, the only detectable pressure rise while using the RIA system occurred while opening the canal, inserting the ball tip reaming rod, reaming with RIA, and

inserting the alignment rod. Therefore, the other specimens only had those steps of a TKA performed and analyzed.

We used the Student's t-test to compare the maximum recorded pressure from performing the procedure with the conventional methods against the maximum recorded pressure from using the RIA system. We also used a one-sample t-test to determine whether the maximum intramedullary pressure associated with both methods was different from 200 mmHg at the specified steps of the procedure. All tests were performed using SPSS V 14.0 (SPSS Inc, Chicago, IL).

### **3.4 Results**

Using the RIA system resulted in lower ( $p = 0.0007$ ) femoral intramedullary pressures compared with performing the steps of a TKA with conventional methods. Proximally, the average maximum pressure decreased from 630 mmHg to approximately 90 mmHg by integrating the RIA system into the initial steps (Table 3). Distally, the average maximum pressure decreased ( $p = 0.001$ ) from 536 mmHg to 67 mmHg. Using the conventional methods, maximum intramedullary pressures occurred during the insertion of the alignment rod (Fig 2). While using the RIA system, the maximum intramedullary pressure occurred with the insertion of the ball tip reaming rod in all of the specimens proximally and in four of the seven specimens distally (Fig 3; Table 4). For both the conventional instrumentation and for the technique using the RIA system, the average maximum pressure occurred at the proximal end of the femur; however, for some of the individual specimens, the maximum

pressure was recorded at the distal end (three of seven on the right femurs and two of seven on the left femurs).

The mean maximum pressure of a simulated TKA using the RIA system was less than 200 mmHg ( $p = 0.004$  proximally and  $p < 0.001$  distally). The mean maximum pressure during the initial steps of a simulated TKA using the RIA system was 89.6 mmHg proximally and 67.2 mmHg distally with a 95% confidence interval between 28.5 and 150.7 mmHg proximally and 39.8 and 82.0 mmHg distally. With the conventional methods, the intramedullary pressure was greater than 200 mm Hg when the alignment rod was inserted into the canal for all specimens (Table 3).

### **3.5 Discussion**

This study hypothesized that using the RIA system in addition to traditional instrumentation during the initial steps of a simulated TKA would result in lower maximum intramedullary pressure compared with performing TKA with only traditional instrumentation. We also tested to see if using the RIA system with the initial steps of a TKA would prevent the maximum pressure from exceeding 200 mmHg. The data suggest adding the RIA to the initial steps of a TKA considerably diminishes the rise in femoral intramedullary pressure.

We note several limitations. The use of cadaver bone cleaved of soft tissue may not perfectly model in vivo pressures. Soft tissues may increase the resistance to outflow of intramedullary contents, and the stripping of these soft tissues may have falsely depressed the

intramedullary pressures recorded while inserting instrumentation into the canal. Additionally, there was no recording of the insertion force or speed of the alignment rods; previous experiments have established these two parameters play a role in increasing femoral intramedullary pressure.<sup>14,19</sup> Despite these potential limitations, the maximum intramedullary pressures recorded during the insertion of the alignment rod using conventional techniques in our experiment ( $630.04 \pm 320.85$  mmHg proximally and  $535.69 \pm 261.77$  mmHg distally) were comparable to the values recorded by Ries et al<sup>19</sup> ( $649.3 \pm 218.5$  mmHg) using the similar technique in vivo.

There might be some concern with removing the fat and bone marrow in the intramedullary femoral canal with the device. Previous research has shown no detrimental costs of removing the fat and bone marrow in the femoral intramedullary canal through in vivo experiments.<sup>2,12,18</sup> Also, the removal of healthy cortical bone through reaming into a narrow femoral intramedullary canal could have some consequences; these biomechanical effects of removing healthy cortical bone cannot be ignored. Harwin et al<sup>7</sup> showed how thinning of anterior metaphyseal bone to a critical level increased the risk of fracture. Aware of this risk, future design modification of the RIA should seek to minimize bone loss as it reams.

In addition to design modifications, procedure modifications could improve the modified technique in this experiment. In one of the seven cases of the modified technique (Table 10), the pressure was above 200 mmHg (213 mmHg) when the ball tip reaming rod was inserted. Mousavi et al<sup>14</sup> showed that as revolution rate of reamer heads increases, the

increase in femoral intramedullary pressure decreases. Since the peak intramedullary pressure occurred most often when leading with the ball tip reaming rod for the modified technique, leading with the RIA could reduce that peak intramedullary pressure.

The main goal of the RIA design was to substantially reduce intramedullary pressure during canal preparation, thereby reducing those risks associated with supraphysiological values. Even though this is the first case to our knowledge of using the RIA with a TKA, based on the results of similar studies, we were confident there would be a significant reduction in maximum femoral intramedullary pressure using the modified technique in comparison to the conventional technique. Experiments have been conducted on femoral intramedullary pressure during reaming and nail insertion in femoral fractures using the RIA or with a similar device on animal models that had similar results as this experiment. Husebye et al<sup>9</sup> reported a lower maximum intramedullary pressure reaming with the RIA ( $33 \pm 8$  mmHg) versus using a traditional reamer ( $188 \pm 38$  mmHg) while reaming pig femurs. Joist et al<sup>10</sup> used a rinsing-suction reamer for reamed intramedullary nailing in which physiological pressure (40 mmHg) was only exceeded during insertion of the guidewire. Importantly, this rinsing-suction reamer achieved considerably lower levels of intravenous fat, as measured by Gurd criteria, compared with a standard AO reamer. Although they did not use a specialized device like the RIA, Amro et al<sup>2</sup> showed using only a suction device decreased the intramedullary pressure of cadaver models and the incidence of fat embolism in vivo from a TKA. Although the RIA was not specifically designed to be used before inserting an intramedullary alignment rod for TKA, our study yielded promising results.

The intramedullary pressure during canal entry using an 8/12.7-mm step drill was not statistically different ( $p>0.05$ ) between the left and right femurs both proximally and or distally. This is noteworthy because even though measurements were not made to compare the force that the surgeon used in opening the canal, his approach was similar for both methods.

We chose to use 200 mmHg as the threshold for fat embolism based on the work of Wenda et al<sup>21</sup> in a sheep model. Pape et al<sup>17</sup> attempted to validate the sheep model and concluded the effect of intramedullary instrumentation in sheep is less pronounced than in humans because the ratios of the femur and vertebral column differ. Although the exact threshold that leads to fat embolism in humans is unknown, it is reasonable to assume if a pressure rise is deleterious for a sheep, then it would be also so in humans. Future work is needed to determine the pressure threshold that leads to fat embolism in humans.

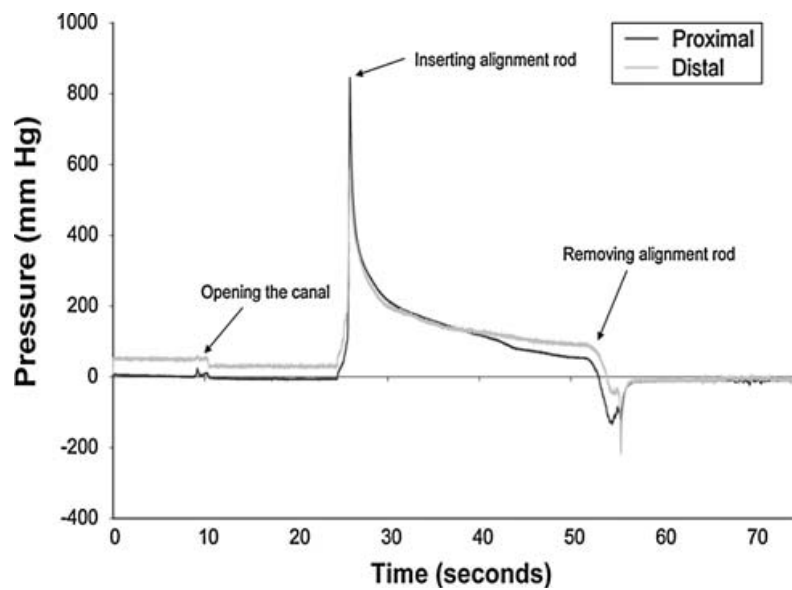
Using the RIA reduced the femoral intramedullary pressure during the initial steps of a TKA and demonstrated the high probability that the pressure would not exceed a critical threshold that may lead to FES. Although these results are promising, clinical studies are required to confirm the approach reduces the risk of emboli.

### **3.6 Acknowledgements**

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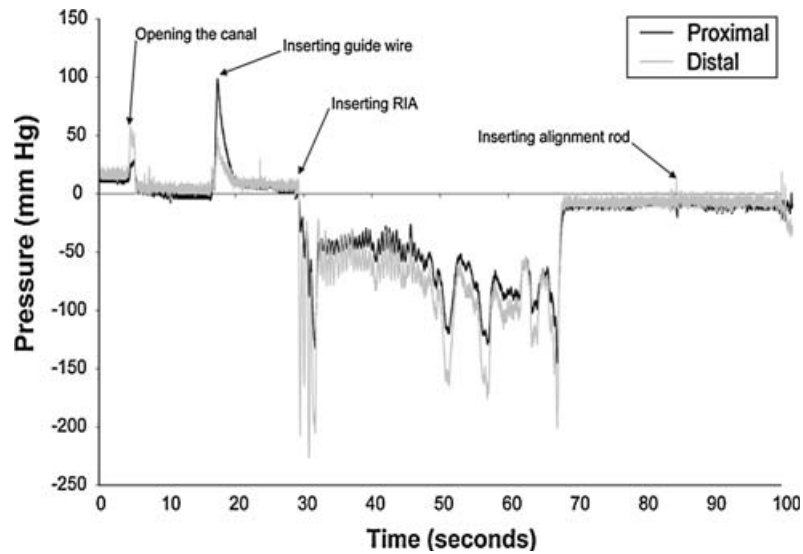


**Figure 9: The reamer/irrigator/aspirator with the reamer head attached.**



**Figure 10: Conventional Method Pressure Reading**

Example pressure reading for the initial steps of TKA when performed with conventional instrumentation. Highest femoral intramedullary pressure occurs while inserting the alignment rod.



**Figure 11: Pressure Method Technique Using RIA**

Example pressure reading for the initial steps of TKA when performed with conventional instrumentation and the reamer/irrigator/aspirator (RIA) system. Highest pressure occurs during insertion of the guidewire for the RIA. Inserting the alignment rod

**Table 3: Peak femoral intramedullary pressure for initial steps of TKA**

Age	Gender	Canal Size (mm)		Cause of Death	Left Femur - Without RIA		Right Femur - With RIA	
		left	right		Peak Proximal Pressure (mm Hg)	Peak Distal Pressure (mm Hg)	Peak Proximal Pressure (mm Hg)	Peak Distal Pressure (mm Hg)
86	Male	14	14	Colorectal Carcinoma	277.51	230.43	8.41	44.26
74	Male	12	13	Cardiorespiratory Arrest	359.82	272.75	25.83	37.91
91	Male	12	11	Congestive Heart Failure	815.71	687.40	98.64	56.95
45	Female	9	10	Respiratory Failure	845.78	587.98	106.55	46.38
50	Male	12	11	Ventricular Tachycardia	677.99	731.83	87.56	71.76
				Acute Myocardial				
71	Female	12	11	Infarction	315.50	327.75	212.61	118.31
				Hypertensive				
72	Male	13	15	Hemorrhagic Stroke	1118.00	911.66	87.56	95.04



**Table 4: Maximum Pressure Through Initial Steps of TKA**

Steps	Location	Max Pressure in mm Hg (mean $\pm$ standard deviation)	
		Conventional Method	Using RIA w/ Conv. Method
Opening the canal	Proximal	4.34 $\pm$ 13.18	8.86 $\pm$ 33.95
	Distal	41.54 $\pm$ 17.00	50.61 $\pm$ 34.18
Inserting ball tip reaming rod	Proximal	-	89.59 $\pm$ 66.04
	Distal	-	60.88 $\pm$ 22.83
Inserting RIA	Proximal	-	12.93 $\pm$ 9.82
	Distal	-	43.05 $\pm$ 24.58
Inserting Alignment	Proximal	630.04 $\pm$ 320.85	2.53 $\pm$ 10.08

## **Chapter 4: Conclusion**

We examined whether the reamer/irrigator/aspirator could effectively increase the canal size and remove intramedullary fat to prevent this pressure increase. We hypothesized using the RIA system in addition to traditional instrumentation during the initial steps of a simulated TKA would result in lower maximum intramedullary pressure compared with performing TKA with only traditional instrumentation. We also asked if using the RIA system with the initial steps of a TKA would prevent the maximum pressure from exceeding 200 mm Hg.

### **4.1 Contributions**

The main contribution was the demonstration that using the reamer/irrigator/aspirator with the technique of a total knee arthroplasty significantly lowers the peak femoral intramedullary pressure during a total knee arthroplasty. A clinical trial is still needed to correlate the lower intramedullary pressure to risk of fat embolism. This experiment shows that the conventional technique of TKA risks fat embolism because the pressure recorded using the conventional technique is above the threshold of a sheep model and the threshold pressure for a person is no greater than the threshold for a sheep<sup>17</sup>. This experiment also showed that once the fat is evacuated from the femoral intramedullary canal, the pressure in the canal is negligible from inserting the alignment rod (Figure 11). This is significant because once the fat is evacuated; the risk of fat embolism related to inserting the alignment rod down the femoral canal is diminished.

## 4.2 Additional Applications

The additional application of this research is verification of the reduced risk of fat embolism using the reamer/irrigator/aspirator in a clinical trial. This research demonstrated that there was a smaller pressure rise using the modified technique with the RIA. However, a clinical trial would compare the occurrence of fat embolism using a transesophageal echocardiography.

Another application for this research is performing a similar cadaver experiment for a total hip arthroplasty. Fat embolism and FES also pose risks to the patient in total hip arthroplasty (THA), as inserting the prosthetic stem into the femoral intramedullary canal (Figure 12) causes elevated pressures<sup>1,18</sup>. Orsini et al<sup>16</sup> found that the mean femoral intramedullary pressure was 737 mm Hg during insertion of the prosthetic implant for cemented THA. Pitto et al<sup>18</sup> found using a bone vacuum technique for cemented THA reduced fat embolism and the incidence of deep-vein thrombosis. The question arises to whether the RIA would have similar success in lowering the femoral intramedullary pressure for a THA as it shown in our study for a TKA. Following the cadaver experiment for THA, a clinical trial of THA could validate the reduced risk of fat embolism.



**Figure 12: X-ray of prosthetic stem inserted in femur for THA**

### **4.3 Future Work**

The future work would involve redesigning the reamer/irrigator/aspirator so it does not remove healthy cortical bone as it reams into the femoral intramedullary canal. This can be accomplished by dulling the cutting edges of the reamer head of RIA or by having the head rotate at a slower angular velocity. Also, the current diameter of the reamer head is 12mm which is larger than some femoral intramedullary canals (Table 3). If the RIA

head and shaft were designed to be 8mm instead of 12mm, then there would be less of a risk of removing healthy cortical bone if the patient had a smaller diameter femoral intramedullary canal.

Another future work of this experiment would be to compare the increase in time of using the RIA to conventional technique or using a standard reamer and suction technique before inserting the alignment rod down the femoral canal. This study would be of importance because time is very valuable in the operating room for two reasons. First, the cost of an operation is about \$1000 a minute for all the staff and equipment and second, the demand for procedures is growing because of the increasing age of the general population. If procedures can be done faster, then more can be done in a given day, which would help to accommodate the aging population

#### **4.4 Summary**

Using the RIA reduced the femoral intramedullary pressure during the initial steps of a TKA and demonstrated the high probability that the pressure would not exceed a critical threshold that may lead to fat embolism and FES. Although these results are promising, clinical studies are required to confirm the approach reduces the risk of fat emboli.

# Using a Reamer Irrigator Aspirator Reduces Femoral Intramedullary Pressure During Simulated Total Knee Arthroplasty

James V. Falk<sup>1</sup>, Jim Green<sup>2</sup>, Stan Kmiec<sup>3</sup>, Robert A. Siston, PhD<sup>4</sup>, Cornel C. Van Gorp, MD<sup>5</sup>

From the Department of Orthopaedics and the Mechanical Engineering Department, The Ohio State University, Columbus, OH and Synthes, Inc., West Chester, PA.



## Introduction

Fat embolism is a common occurrence following total knee arthroplasty (TKA) [1, 2]. Previous research has shown a positive correlation between an increase in femoral intramedullary pressure and the number of fat particles observed in the lungs postoperatively when a TKA was performed using traditional instrumentation [3, 4]. Efforts to reduce the femoral pressure during TKA include using differently sized and shaped intramedullary instrumentation and over-drilling the canal [5], but these approaches have not eliminated the risk of post-operative embolism. Nishie et al [6] demonstrated a cadaver study that decreasing the intramedullary content of the femur prior to reaming decreased the pressure produced during instrument insertion. This study compares the femoral intramedullary pressure during the initial steps of a simulated TKA performed with conventional instrumentation against the intramedullary pressure of a simulated TKA performed with conventional instrumentation and the Reamer Irrigator Aspirator (RIA, Synthes, Philadelphia, PA). We hypothesize that using the RIA will result in less of an increase in femoral intramedullary pressures than using only conventional instrumentation during the initial steps of a total knee arthroplasty.

## Methods

We performed a simulated TKA on 14 femurs (7 pairs) from freshly frozen cadavers. The femurs had all soft tissues removed and were measured diagonally to custom fixtures. An experienced orthopaedic surgeon performed the initial steps of TKA on all specimens. On the left femur, he opened the canal with an 8.1 x 7 mm step drill (Zimmer, Warsaw, IN) and inserted an 8 mm fixed alignment rod (Zimmer, Warsaw, IN). On the right femur, he opened the canal with the same step drill, but then inserted a 12 mm RIA and reamed for the RIA. The RIA was used with the 12 mm RIA until the femur was fully reamed. During all simulated TKAs, intramedullary pressure was recorded with the pressure transducer.



We used the student's t-test to compare the maximum recorded pressure from performing the procedure with the two different methods. All statistical tests were performed using SPSS V 14.0 (SPSS Inc., Chicago, IL) and the level of significance was set at 0.05.



Figure 1: Image of a Reamer Irrigator Aspirator (RIA) device. Figure 2: The Reamer Irrigator Aspirator (RIA) device in a simulated TKA setup.



Figure 3: The Reamer Irrigator Aspirator (RIA) device in a simulated TKA setup.

## Results

- Using the RIA resulted in statistically significant lower intramedullary pressures compared to performing the steps of a TKA with conventional instrumentation on the femur (p<0.001) (Table 1).
- Approximately, the average maximum pressure decreased from 650 mmHg to approximately 50 mmHg, a decrease of 88%, by integrating the RIA system into the initial steps (Table 1).
- Distinctly, the average maximum pressure decreased from 258 mmHg to 87 mmHg, a decrease of 67%, by integrating the RIA system into the initial steps (Table 1).
- The maximum pressure with the initial conventional method of TKA occurred during the insertion of the alignment rod (Figure 4).
- Using RIA along with the conventional TKA method, the average maximum pressure occurred during insertion of the RIA by reaming rod (Figure 5).

Table 1: Mean Maximum Intramedullary Pressure for Initial Steps of TKA with and without RIA.

Step	Conventional TKA	RIA TKA
Age	68.5 ± 12.5	68.5 ± 12.5
Gender	12 M, 2 F	12 M, 2 F
Height	171.2 ± 10.2	171.2 ± 10.2
Weight	70.2 ± 10.2	70.2 ± 10.2
Step 1: Opening the canal	650 ± 100	50 ± 10
Step 2: Inserting the RIA	258 ± 50	87 ± 10
Step 3: Inserting the alignment rod	650 ± 100	50 ± 10
Step 4: Final pressure	650 ± 100	50 ± 10

Table 2: Mean Maximum Intramedullary Pressure for Initial Steps of TKA with and without RIA.

Step	Conventional TKA	RIA TKA
Age	68.5 ± 12.5	68.5 ± 12.5
Gender	12 M, 2 F	12 M, 2 F
Height	171.2 ± 10.2	171.2 ± 10.2
Weight	70.2 ± 10.2	70.2 ± 10.2
Step 1: Opening the canal	650 ± 100	50 ± 10
Step 2: Inserting the RIA	258 ± 50	87 ± 10
Step 3: Inserting the alignment rod	650 ± 100	50 ± 10
Step 4: Final pressure	650 ± 100	50 ± 10

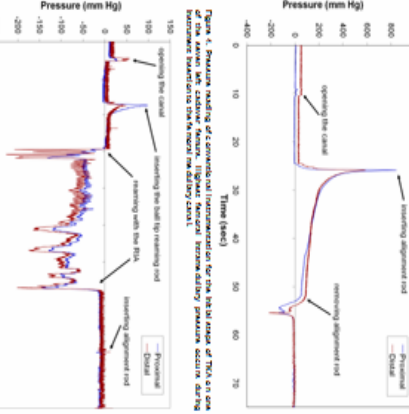


Figure 4: Pressure (mm Hg) vs Time (sec) graph showing pressure during TKA steps.

## Discussion

- The data suggest that using the RIA during the initial steps of a TKA would result in lower femoral intramedullary pressure than using only conventional instrumentation and lead to a reduced risk of fat embolism.
- This is the first instance of using the RIA for total knee arthroplasty since the RIA was developed for femoral fracture surgery.
- There was no recording of the insertion force or speed of the alignment rod; previous experiments have established these two parameters play a role in increasing femoral intramedullary pressure [3].
- The maximum intramedullary pressures recorded during the insertion of the RIA were significantly lower than the maximum pressures recorded during the insertion of the alignment rod (650.04 ± 130.85 mmHg vs 261.77 ± 261.77 mmHg, p < 0.001).
- Future work should be conducted using RIA to investigate the reduced risk of fat embolism in a clinical trial.

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